Products Liability in the Pharmaceutical Industry

Jason Dooney, Richard J Hunter JR.*

Department of Economics and Legal Studies, Seton Hall University

Abstract

This article addresses the issues relating to products liability in the pharmaceutical industry. It outlines the drug approval process and the pressures inherent in the system arising from competition from generic drugs and affordable health care organizations in the context of two infamous drug recalls: Baycol and Vioxx. Finally, the paper includes several appendices dealing with the drug approval process, the nature of product warnings, principles of federal preemption, the “learned intermediary” rule, and expected health care expenditures for 2012-2013.

Keywords: Products liability, Drug approval process, Generic drugs, Affordable health care organizations, Baycol, Vioxx.

Introduction

It is no secret that the cost of health care is one of the most widely discussed topics in both the developed and developing world. This is especially true in the United States where the debate rages on as a result of the introduction of Obamacare and continued efforts to “bring down the cost curve” of medical services. Prescription drug costs make up one of the central points of this debate. By 2004, prescription drug use had risen “among people of all ages, and use increases with age. Five out of six persons 65 and older are taking at least one medication and almost half the elderly take three or more” [1]. Perrone [2] reported that the number of extraordinary price hikes on drugs doubled between 2000 and 2008.”

The GAO (Government Accountability Office) report indicated that the rise was attributable to industry consolidation and price hikes by third-party providers who repackaged drugs [2].

As can be demonstrated in the chart below, as of 2000, prescription drug costs made up 10% of every dollar spent on health care, and the trend has continued. [Appendix I – Health Care Costs 2013-2014]. While this percentage still pales in comparison to the combined 51% that hospital care (31%) and physician services (20%) account for, prescription drug costs is the fastest rising segment of the health care dollar breakdown.

National Health Expenditures, 2010

The high cost of branded pharmaceuticals [3,4], which can consist of both prescription and over-the-counter drugs, can be attributed to a wide variety of factors including the process of bringing a drug to market, the influence of generic competition placing pressure on the prices of branded drugs, the growing reluctance of insurance companies to cover branded medications when generics are available, and the rise of affordable care organizations. As noted by Tomas Philipson [5], “And indeed they [generics] do lower the prices, which routinely decline by 60% or more through generic competition after patents expire. As a result, brand name manufacturers lose roughly about 80% of their market share.”

All of these factors contribute to a patient paying higher and higher prices for some branded medications. It is also worth noting that many of these factors have only risen to prominence in the last ten years. In the mid to late 1990s, or as some may say the “glory days of pharmaceuticals,” many of these problems did not exist at all. [6]. In this context, a question must be addressed: What affects do products liability cases have on the cost of branded medications? Additionally, have the days of mega products liability lawsuits (class action, mass torts) (e.g., Dier v. Merck & Co. (In re Vioxx Prods. Liability Litigation), 2011; [7] against pharmaceutical companies passed and will there actually be a decline in the future? Before addressing these questions, the most important cost driver must be looked at more closely-the act of bringing a new drug to the market.

**New Drug Approval Process and Timeline**

It would be fair to say that few consumers truly know how much time, effort, and expense goes into bringing a new branded medication to market. It takes, on average, twelve years and over $350 million to get a new drug from the laboratory onto the pharmacy shelf. [8]. (A study published in 2010 in the journal Health Economics, including an author from the United States Federal Trade Commission, came up with a higher estimate of ~$1.2 billion.) [9]. A new molecule initially spends two to three years being studied on animals in pre-clinical trials. If a molecule gets FDA approval to be studied on humans, it then enters three phases of clinical trials. Only one in 1000 of the compounds that enter laboratory testing will ever make it to human testing [8]. The primary differences between the three phases of human trials are number of patients and duration of trials. (See, e.g., Fain, Nachman & Rutkow) [10]. As a drug moves through phases one, two, and three, the number of patients in each trial increases, as well as the time patients spend on the medication in each trial. If a drug makes it through all three phases, it is then ready to be passed to the FDA for data review and approval. This process can take between two and three years. If the drug finally gains FDA approval, only then can it be made available for physicians to prescribe. (See Appendix II- Drug Approval Process.)

As noted, it may take an average of twelve years for a drug to pass through all its trials as it moves from test tube to patient. The difficulty is that pharmaceutical companies generally have patent protection of a molecule for twenty years on average [11]. The general public, however, may believe that patent protection begins when the drug becomes available for sale. This is not the case. Patent protection begins when a molecule is first registered with the patent office before animal testing begins. [12]. This means that if a drug is fortunate enough to receive final FDA approval for sale, the company only has, on average, eight years remaining to recover the cost of producing the medication and to turn a profit.

To make matters even more complicated from a cost perspective, the vast majority of molecules that a pharmaceutical company tests ultimately never get approved. A drug can be withdrawn at any time during the twelve year testing period. Obviously, the further into the testing phases a drug gets, the more costs begin to add up. There have been cases where a drug was in the FDA approval stage and the company was so confident that it would be approved that it began creating marketing materials and hiring sales staff to promote the product, only to have the drug fail to receive final FDA approval. The research-based pharmaceutical industry currently invests some $12.6 billion a year in new drug development. Historically, the drug development figure doubles every five years [8]. Therefore, not only does an approved drug have to recoup its own costs in an eight to ten year period, it also has to make up for the cost of drugs that never get approved.

**Recent Success Rates of New Drug Approvals**

The success rates for new drug approvals have been steadily declining ever since the turn of this century. This decline is due in large part to the results of past products liability cases and the potential threats posed by new ones. At the same time, the FDA has made its approval processes more and more stringent over the last ten to
fifteen years. It would even be fair to say that many blockbuster drugs that are available today would never receive approval if they were brought before today’s FDA. For example, Lipitor, a cholesterol lowering agent and the biggest selling drug in the world for many years, would probably not receive approval today based on the studies the manufacturer (Pfizer) ran years ago. In those studies, there were many high risk patients who were placed in placebo groups. Today, this would be considered unethical because Pfizer would be putting those patients in the placebo groups at unnecessary risk by leaving them completely untreated for dangerous conditions.

How much worse have FDA approval rates become in recent years? A recent study funded by Sagient Research Systems and the Biotechnology Industry Organization (BIO) [13] looked at the likelihood of approval rates for drugs from 835 drug developers including “Big Pharma,” small biotechs, and specialty companies. The authors analyzed success rates for over 7,300 independent drug paths. They found the likelihood of approval from Phase 1 to be about 10% for all indications, and 15% for lead indications. From Phase 1 to Phase 2 success rates are about 65%; from Phase 3 to new drug applications success rates fall again between 60% and 68%. The biggest drop off comes moving from Phase 2 to Phase 3, with only 32% of all indications advancing [13].

There are two possible reasons why this study yielded such negative results. First, the study included small biotech companies that generally have fewer resources and less experienced scientific teams with which to bring a new drug through all of the required phases, thus naturally increasing their risk of failure. Second, and far more likely, is the timing of this study. This was one of the most recent studies evaluating FDA drug approval rates. Therefore, this study included all drugs susceptible to the new, stricter FDA regulation policies. These stricter regulations are a direct result of past issues and experiences with mass products liability lawsuits.

**Pressure from Generic Competition and the Rise of Affordable Care Organizations**

In addition to the exorbitant costs of developing a new medication and bringing it to market, pharmaceutical companies must deal with growing cost pressures from generic alternatives and from affordable care organizations. Although these cost pressures have little to do with litigation costs, they are worth mentioning in order to better understand the total picture in which medications play a role in the financial healthcare landscape.

With cost savings at such a premium in the health care market today, generic medications are more widely used than ever. This generic push comes from three main sources; insurance companies, pharmacies, and affordable care organizations. Although insurance companies will offer the choice of branded medications for their patients, the branded medications are always offered at a Preferred Branded (Tier 2) or Non-Preferred Branded (Tier 3) co-pay. While a Tier 2 medication will always be more affordable than a Tier 3 medication, they will all be more expensive than a generic (Tier 1) option. In addition, many insurance companies will try to force their customers to use a generic option by requiring either a Prior Authorization, which requires a lot of time and paperwork on the part of the doctor, or a Step Edit, which states that a patient must try and fail to secure a generic option before a branded medication can be considered [12].

Pharmacies also heavily affect the generic medication landscape. They will often suggest generic alternatives to their customers as a cost saving alternative. This is often done under the guise of doing “what’s best” to help their customers save money. However, it is worth noting that pharmacies are businesses first and foremost. They have the largest profit margins on generic medications and often offer bonuses to pharmacists and lab techs who switch over a certain percentage of branded prescriptions to a generic alternative. While many times this is done with the patient’s best interests at heart, however, it has been alleged that sometimes patients may be switched to an inferior medication that can put them at greater risk because of financial and not medical considerations [14].

Finally, affordable care organizations (ACO) are becoming a bigger and bigger force in the health care world. According to the Centers for Medicare and Medicaid Services (2010), an ACO is “an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it.” Under the Patient Protection and Affordable Care Act of 2010 [15] the groups of providers that are eligible to participate as ACOs include:
- Professionals in group practice arrangements;
- Networks of individual practices of professionals;
• Partnerships or joint venture arrangements between hospitals and professionals;
• Hospitals employing professionals; and
• Other groups of providers that HHS determines appropriate [16].

In a more practical sense, ACOs are basically a group of individual doctors coming together and forming a large organization of doctors. This is done to give them “strength in numbers,” most especially when it comes to negotiating reimbursement rates with insurance companies. The larger the group becomes, the more say they have in deciding if their members will have the freedom to write branded medications instead of insurance companies making the decisions for them.

The Cost Effect of Products Liability Cases on the Pharmaceutical Industry

All of the cost concerns facing pharmaceutical companies discussed so far are relatively easy to monitor and determine. The cost effect of products liability lawsuits, as it turns out, is very difficult to accurately measure. However, it is fairly easy to assess the potential positives and negatives of products liability suits in the pharmaceutical industry. A positive impact of a threat of a product liability lawsuit is that it may lead to more thorough pre-launch drug testing, more complete and accurate warnings being issued, and a decreased likelihood of a pharmaceutical company withholding negative information from the FDA. (Appendix III- Nature of Required Warnings). Potential negatives of products liability cases include higher drug costs due to increased testing and decreased drug approval rates, fewer products potentially available, and a potential decrease in new treatment options, especially in areas where the risk of lawsuits may be higher. However, putting a price tag on these affects can be difficult, if not impossible.

A study of the economic impact on the pharmaceutical industry by the RAND group in 2013 came to this very conclusion by stating, “Economic effects of pharmaceutical product liability, however, are surprisingly difficult to analyze empirically, and there is little direct empirical knowledge about them” [17]. Further evidence can be seen—or more specifically not seen—on the health care dollar breakdown described earlier. This cost to health care, however, is not specifically addressed in the analysis.

There are at least three potential reasons why the cost of products liability claims against pharmaceutical companies can be so difficult to quantify. First, many companies, especially smaller companies, choose not to pursue research of a relating to a possible new drug if the potential risk of products liability claims is high.

This is especially true in categories of drugs such as vaccines or in specialty “niche disease” areas where a newly developed drug may only be helpful to a few hundred people throughout the United States and thus may not have a large market potential. It may be a cold fact, but if the financial benefit of making a drug is not present and ascertaining from a financial standpoint, then the drug may never be developed, making it virtually impossible to weigh the possible effects of products liability claims.

Second, it is still the case that the top two reasons for products liability lawsuits against pharmaceutical companies are erroneous, factually incorrect, or incomplete safety information and off-label promotion. However, as mentioned earlier, a large portion of today’s prescription drug market is made up of generic medications. On June 24th 2013, in Bartlett v. Mutual Pharmaceutical Company (2013), the United Supreme Court reversed a 2011 ruling against generic drug manufacturer, Mutual Pharmaceuticals, holding that generic drug manufacturers were not responsible for the safety data relating to their products [18]. The Court relied on a principle termed preemption to invalidate a state regulation relating to the responsibility of a generic drug manufacturer. (Appendix IV- Principles of Preemption). The Court noted: “Because it is impossible for Mutual and other similarly situated manufacturers to comply with both state and federal law, New Hampshire’s warning-based design-defect cause of action is preempted with respect to FDA-approved drugs sold in interstate commerce [19]. This ruling will make it very difficult to sue a generic drug company in the future on the basis of improper warnings [20].

Since generic drugs are not promoted by sales people, there will not generally be any off-label promotion via a “learned intermediary” Fullington v. Pfizer, Inc., 2013 [21, 22] at least as to issues relating to safety data [23]. With generic medications now making up the majority of prescriptions written in the United States, this decision of the United States Supreme Court may greatly reduce products liability claims in the future, making its economic impact even smaller. (Appendix V- The Doctrine and the Restatement (Third) of Torts).
Finally, with more stringent regulations for new drug approvals and the heavy fines levied by the FDA in the past for off-label promotion, the incidences of products liability claims have been decreasing over time [24]. As stated in the RAND report, “Most of the direct evidence available about product liability pertains to particular drugs, and almost all of that evidence pertains to events that occurred a decade or more ago.” [17] Even though it may seem like there are still a large number of ongoing products liability lawsuits against pharmaceutical companies, most of the judgments that are being paid out arose from lawsuits commenced years ago before the FDA approval process became more stringent. This is not to say that products liability claims against pharmaceutical companies will cease to exist—the data simply suggests that the newer, stricter rules in place by the FDA will make it less likely to see massive settlements like the $3 billion settlement Glaxo Smith Kline paid out in 2012 for a wide variety of violations stemming back to the early part of the century [25].

An Analysis of Two Landmark Pharmaceutical Products Liability Cases

However, before reaching any conclusion on the cost effects of products liability cases generally on pharmaceutical companies, it is worth taking a look at two of the biggest cases of drug recalls over the last fifteen years—Baycol and Vioxx—that prompted the movement toward a more rigorous FDA approval process.

**Baycol (Cerivastatin) 2003**

Baycol was a cholesterol-lowering agent made by Bayer Pharmaceuticals that belonged to a class of drugs called Statins. Other notable drugs in this category are Zocor, Lipitor, and Crestor. The most dangerous side effect of this class of drugs is rhabdomyolysis (muscle death). In the Statin class as a whole myalgia (muscle pain) is the most common side effect. With all the other drugs in the Statin class, a case of rhabdomyolysis is an extremely rare occurrence. However, it was this side effect that was ultimately Baycol’s undoing [26].

As noted by Shapiro, Ruttenberg, and Leigh [27] “problems began to occur when people took Baycol in higher doses, particularly in elderly women with smaller bodies. Reports of side effects that physicians sent to the FDA from 1990 to 2002 indicated that the probability of Baycol-induced rhabdomyolysis was 65 times higher than the probability of this side effect in all other statins combined. A subsequent FDA-supervised analysis found that rhabdomyolysis-related mortality rates for Baycol users were 16 to 86 times higher than for users of other statins.”

By 2003, in fact, the drug had become widely popular and 700,000 Americans were taking Baycol. The drug was eventually linked to 31 deaths in the United States from muscle destruction and at least 9 more fatalities abroad [28, 29]. It was the Baycol recall that sparked the FDA to take a hard look at their drug approval process. In fact, many in the public blamed the FDA as much as Bayer for Baycol's problems. Paul Dowering of the University of Florida's College of Pharmacy was quoted as saying “This recall highlights a broader problem, and that is the inability of the drug approval process to predict what the true nature of any drug is, based solely on the data required for an NDA [new drug application].” At that time, Baycol was the 12th prescription drug taken off the U.S. market for dangerous side effects since 1997 [28]. The products liability potential was truly enormous.

**Vioxx (Rofecoxib) 2004**

The Vioxx recall was very different than the Baycol recall in that the problem with Vioxx was less about the efficacy of the drug itself and more related to Merck issuing misleading safety information and, most shockingly, allegedly fabricating study results [30]. The number of deaths attributed to Vioxx was catastrophically higher than those related to Baycol. However, the deaths associated with Vioxx came about because of the misleading safety data. Specifically, Vioxx was being used in the treatment of wrong patients. There are many doctors that would argue even today that Vioxx was a very good drug when used in the treatment of appropriate patients. No doctor would make that same claim when it came to Baycol.

Vioxx was a non-steroidal anti-inflammatory drug (NSAID) as well as a prescription painkiller. At its height, Vioxx was being used in as many as 80 million people worldwide. Merck’s major difficulty began when it ran studies to prove that Vioxx caused fewer gastrointestinal issues than other NSAIDs. When Merck eventually published these studies, it conveniently left out the negative data that showed that Vioxx drastically increased the rate of heart attacks in its patients. As noted by Culp and Berry [31]: “as reports slowly filtered to the media that long before its removal of Vioxx from the marketplace, Merck knew that Vioxx was a dangerous drug and they nevertheless marketed it aggressively to doctors and an unsuspecting public.”
At the time that Vioxx was recalled in 2004, more than 38,000 deaths were related to Vioxx use, and up to 25 million Americans had taken the drug [8]. Vioxx caused so much damage that some have called it the worst drug disaster in history [8]. The Vioxx scandal wasn’t just devastating to the injured patients and their families; it also underscored serious problems within the FDA itself. Although “Merck and Vioxx have had a stormy relationship since the Food and Drug Administration’s May 1999 approval of Vioxx” [31] many continued to speculate that the New Jersey-based Merck and the FDA worked together to keep the drug on the market and quiet the health concerns [8]. This is another example of a situation that is very unlikely to occur under the revamped, rigid FDA guidelines. The reaction to the Vioxx debacle is another reason why a strong case can be made for a likely decrease in products liability cases being filed in the future.

Some Tentative Observations or Conclusions

The inquiries raised initially questioned the cost effect of products liability lawsuits on the pharmaceutical industry, as well as the future of big products liability (mass tort) cases against pharmaceutical companies. It is fair to say now that the results produced by the RAND group are accurate. It is virtually impossible to put a dollar amount on the overall effect that products liability cases have on the industry as a whole. Lawsuits generally pertain only to specific medications and specific manufacturers and not to the industry as a whole. This allows a particular company to gauge the effect of a lawsuit on itself using a traditional “risk-utility” analysis” (Phillips v. Kimwood Machine Co., 1974; Owen, 1997) [32], but it is difficult to assess the cost effect on the overall industry.

Lawsuits can be avoided entirely by opting not to produce a medication whose risk of a lawsuit may far outweigh their financial reward. This, of course, may leave some people without a medication that could potentially improve their life greatly. However, this may be more of a moral or societal issue, rather than as one of cost effectiveness.

While there have been major financial implications attached to products liability cases, product liability lawsuits have undoubtedly changed the industry for the better. Most of the major products liability lawsuits originated in the late 1990s and early 2000s. As a result of past lawsuits, the FDA has changed the way they look at new drug approvals. Although this has led to far fewer new drug approvals over the last ten years, doctors and patients can have confidence that the new drugs that do get approved are rigorously tested before approval. In addition, pharmaceutical companies are holding themselves to higher ethical standards. Ever since these products liability lawsuits were commenced at the beginning of the century, most of the big pharmaceutical companies have signed on to an agreement called the PHARMA Code [33]. This agreement is essentially self-policing and self-enforced by the participating pharmaceutical companies and it outlines a code of ethics that all companies will abide by.

This Code pertains to all aspects of the industry, including testing and promotion. What is clear is that all of the outcomes that were derived from past products liability cases will make the industry stronger and should ultimately lead to fewer cases brought against the pharmaceutical industry in the future: a good result for both consumers and the industry [34-38].

Appendix I: Health Care Costs 2012-2013

For a discussion of health care costs for 2012-2013, see Department of the Census, “Health & Nutrition: Health Expenditures”. The information includes: National Health Expenditures-Summary; National Health Expenditures by Source of Funds; National Health Expenditures by Source of Funds and Type of Expenditure; Health Consumption Expenditures—Per Capita Spending by Type of Expenditure and Source of Funds; Health Consumption Expenditures by Type of Expenditure and Source of Funds; Personal Health Care Expenditures by Source of Funds; National Health Expenditures by Sponsor; Hospital Care, Physician and Clinical Services, Nursing Home Care, and Prescription Drug Expenditures by Source of Funds; Consumer Price Indexes of Medical Care Prices; Average Annual Expenditures Per Consumer Unit for Health Care; and Retail Prescription Drug Sales.

Appendix II: Drug Approval Procedures

The FDA requires the following sequence of events before approving a drug.

- Preclinical Testing: A pharmaceutical company conducts certain studies before the future drug is ever given to a human being. Laboratory and animal studies must be done to demonstrate the biological activity of the drug against the targeted disease. The drug must also be evaluated for safety. These tests take on the average 3 1/2 years.
• **Investigational New Drug Application (IND):** The pharmaceutical company files an IND with the FDA to begin testing the drug in people. The IND becomes effective if the FDA does not disapprove it within 30 days. The IND must include the following information: the results of previous experiments; how, where and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the body; any toxic effects found in the animal studies; and how the compound is manufactured. The IND must also be reviewed and approved by the Institutional Review Board where the studies will be conducted.

• **Phase I Clinical Trials:** Phase I studies are usually the first tests of a drug under development in healthy volunteers. These studies involve about 20 to 80 volunteers. The tests determine a drug's safety profile, including the safe dosage range, plus how the drug is absorbed, distributed, metabolized and excreted, and the duration of its action. Phase I trials take on the average 1 year.

• **Phase II Clinical Trials:** These are slightly larger studies that are done in patients with the disease for which the drug is intended. This phase is usually designed to identify what are the minimum and maximum dosages. The trials generally involve 100 to 300 volunteer patients and are controlled in design. They are done to assess the drug's effectiveness. Phase II typically takes about 2 years.

• **Phase III Clinical Trials:** These are the definitive, large randomized trials that are submitted to the FDA in order to obtain approval of a drug. This phase examines the effectiveness as well as the safety (adverse events) of the new drug. Phase III trials usually involve 1,000 to 3,000 patients in clinics and hospitals. Patients are usually asked a list of possible side effects, often derived from what was observed in phase II studies. Patients are also free to report any other side effects that occur while they are on the new drug or the placebo (the "sugar pill" that is given to a percentage of patients in a trial study). Phase III takes on the average 3 years.

• **New Drug Application (NDA):** Following the Phase III Clinical Trials, the drug manufacturer analyzes all the data from the studies and files an NDA with the FDA (provided the data appear to demonstrate the safety and effectiveness of the drug). The NDA contains all of the data gathered to date about the drug. (An NDA typically consists of at least 100,000 pages.) The average NDA review time for new drugs approved in 1992 was close to 30 months (2 1/2 years).

• **Phase IV Studies:** Phase IV is any organized collection of data from patients who are taking a drug that has already received approval from the FDA. In Phase IV studies, patients may check boxes on a list (as in phase III studies) or they may just report other symptoms. Phase IV studies are commonly called "post-marketing studies.

**Appendix III: Adequacy of Product Warnings**

There are three criteria that are used by courts concerning the adequacy of warnings:

- A warning must be displayed in such a way so as to reasonably catch the attention of the person expected to use the product. This element deals with such factual questions as size, position, and even the color of warnings;
- A warning must fairly apprise a reasonable user of the nature and extent of the danger and not minimize the danger;
- A warning must instruct the user how to use the product so as to avoid the danger... essentially how to safely use the product [39].

**Appendix IV: Principles of Preemption**

There are four major aspects of the preemption discussion; that is, deciding whether a specific state regulation or statute would or would not be preempted in the absence of an express preemption clause:

- Congress may intend to “occupy the field” in a given area because federal regulation may be so persuasive or the federal interest so dominant, as in federal labor legislation or nuclear waste disposal; [40];
- Where a state law or statute conflicts with a federal law;
- Where a state law or statute stands as an obstacle to the accomplishment and execution of the purposes stated by Congress; and
- Where it would be a physical impossibility to comply with both federal and state law. [41].

**Appendix V: The “Learned Intermediary” Rule**

The Third Restatement explicitly includes the “learned intermediary doctrine” in Section 6:
A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

- Prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with instructions or warnings; or
- The patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

The “learned intermediary doctrine” has been held not to apply when prescription drugs have been marketed directly to the consumer under the circumstances of that case. [42]. An exception has also been applied in cases of mass inoculations, where the health-care provider is not in a position to evaluate the risks of using the drug or to relate those risks to the patients (Restatement (Third) of Torts, Section 6, Comment e, 1997), or where the FDA requires that direct warnings be given to the patient [43].

References
18. Croom Brittany (2014) Buyer Beware: Mutual pharmaceutical co. v. bartlett continues to alter the


42. Perez v. Wyeth Laboratories, Inc., 734 A.2d 1245 (Supreme Court of New Jersey, 1999).